Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PROTOCOL INFORMED CONSENT

Date of Visit: _____/_____/_________
mmm dd yyyy

Date Informed Consent Signed: _____/_____/_________
mmm dd yyyy

DATABANK INFORMED CONSENT

97 ☐ Databank Informed Consent not obtained

Date Informed Consent Signed: _____/_____/_________
mmm dd yyyy

SPECIMEN BANKING INFORMED CONSENT

97 ☐ Specimen Banking Informed Consent not obtained

Date Informed Consent Signed: _____/_____/_________
mmm dd yyyy

See Version 2 of the CRF at the end of this document.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

INCLUSION CRITERIA

Note: *Any "No" response in this section disqualifies the subject from the study, unless prior approval has been obtained from the sponsor.*

	No	**Yes**	**N/A**
1. Male or female ≥ 1 year and ≤ 12 years of age	0 ☐	1 ☐	
2. Confirmed diagnosis of Cystic Fibrosis: • sweat chloride > 60 mEq/L by quantitative pilocarpine iontophoresis; and/or • a genotype with two identifiable mutations consistent with CF or an abnormal nasal transepithelial potential difference **and** • one or more clinical features consistent with CF	0 ☐	1 ☐	
3. ***Participants >15 months of age:** New onset of *Pa* positive respiratory culture within 6 months prior to Baseline Visit:			98 ☐
a) first lifetime documented *Pa* positive culture; **OR**	0 ☐	1 ☐	98 ☐
b) *Pa* recovered after at least a 2 year history of *Pa* negative respiratory cultures (≥ 1 culture/year)	0 ☐	1 ☐	98 ☐
4. ***Participants 12-15 months of age:** at least one documented *Pa* positive respiratory tract culture since birth or CF diagnosis	0 ☐	1 ☐	98 ☐
5. Clinically stable: • no evidence of significant respiratory symptoms and/or physical or chest radiograph findings at screening that would require administration of IV anti-pseudomonal antibiotics, oxygen, and/or hospitalization	0 ☐	1 ☐	
6. Signed informed consent by parent or legal guardian and applicable assent.	0 ☐	1 ☐	

**Select appropriate age criteria for participant. If participant is >15 months of age, also select either subcriteria a) or b). Any non-applicable age or subcriteria should be marked "N/A".*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

EXCLUSION CRITERIA

Note: *Any "Yes" response in this section disqualifies the subject from the study, unless prior approval has been obtained from the sponsor.*

		No	Yes
1.	History of aminoglycoside hypersensitivity or adverse reaction to inhaled aminoglycoside.	0 ☐	1 ☐
2.	History of hypersensitivity or adverse reaction to ciprofloxacin or other fluoroquinolone.	0 ☐	1 ☐
3.	History of persistent, unresolved hearing loss documented by audiometric testing on at least two occasions and not associated with middle ear disease or an abnormal tympanogram.	0 ☐	1 ☐
4.	Abnormal renal function at Baseline Visit (serum creatinine > 1.5 times the upper limit of normal for age).	0 ☐	1 ☐
5.	Abnormal liver function tests at Baseline Visit (ALT and/or AST > 2 times the upper limit of normal range).	0 ☐	1 ☐
6.	Administration of any investigational drug within 30 days prior to the Baseline Visit.	0 ☐	1 ☐
7.	Administration of loop diuretics, phenytoin, warfarin, theophylline or other methyl-xanthines ≤ 30 days prior to Baseline Visit.	0 ☐	1 ☐
8.	Administration of more than one course (at least 10 continuous days of therapy) of IV anti-pseudomonal antibiotics or more than one course (at least 28 continuous days of therapy) of inhaled anti-pseudomonal antibiotics. Antibiotics must be completed > 30 days prior to the Baseline Visit.	0 ☐	1 ☐
9.	Chronic macrolide use (more than 90 day duration) within 3 months prior to the Baseline Visit.	0 ☐	1 ☐
10.	Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the Participant or the quality of the data.	0 ☐	1 ☐

The CRF data below was not submitted

I certify that I have reviewed source documentation and that all inclusion / exclusion information is accurate.

Signature: ________________________________ Date: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

DEMOGRAPHICS

Date of Birth: ______/______/___________
mmm dd yyyy

Sex: 1 ☐ Male 2 ☐ Female

Race/Ethnicity (check one):

1 ☐ Caucasian (not of Hispanic origin)
2 ☐ Hispanic
3 ☐ American Indian or Alaskan Native
4 ☐ African-American (not of Hispanic origin)
5 ☐ Asian or Pacific Islander
99 ☐ Other, specify: ________________________

REPRODUCTIVE STATUS

Female is: 1 ☐ Pre-menarche 2 ☐ Post-menarche 98 ☐ N/A

DIAGNOSIS

Sweat Chloride Test 97 ☐ Not Done Date of Test: ______/______/___________
mmm dd yyyy

Result: ___ ___ ___ mEq/L

CF Genotype 97 ☐ Not Done Date of Test: ______/______/___________
mmm dd yyyy

this genotype data has not been submitted.

Mutation #1.
1 ☐ Delta F508
2 ☐ Unidentified
99 ☐ Other, specify: ____

Mutation #2.
1 ☐ Delta F508
2 ☐ Unidentified
99 ☐ Other, specify: ____

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

MEDICAL HISTORY

Medication Allergies: 0☐ Check if None

1. ______________________
2. ______________________
3. ______________________
4. ______________________
5. ______________________
6. ______________________
7. ______________________
8. ______________________

No.	*Body System **Indicate Body System only if "Other" is used*	Details	Resolved	Inactive	Active
1.	☐ ________		0☐	1☐	2☐
2.	☐ ________		0☐	1☐	2☐
3.	☐ ________		0☐	1☐	2☐
4.	☐ ________		0☐	1☐	2☐
5.	☐ ________		0☐	1☐	2☐
6.	☐ ________		0☐	1☐	2☐
7.	☐ ________		0☐	1☐	2☐
8.	☐ ________		0☐	1☐	2☐
9.	☐ ________		0☐	1☐	2☐
10.	☐ ________		0☐	1☐	2☐
11.	☐ ________		0☐	1☐	2☐
12.	☐ ________		0☐	1☐	2☐

Please ensure all significant medical history and medical procedures are reviewed for the following body systems:

01=General Appearance
02=Skin
03=Lymph Nodes
04=HEENT
05=Respiratory
06=Cardiovascular
07=Gastrointestinal
08=Urinary
09=Neurologic
10=Hematologic
11=Endocrine
12=Musculoskeletal
13=Surgical
99=Other

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

HISTORY OF ANTI-PSEUDOMONAL ANTIBIOTIC USE
***(Regardless of Indication)* from birth to Baseline Visit**

0☐ None

Line #	Medication	Route *(IV, INH, PO)*	Start Date *(mmm/dd/yyyy)*	Stop Date *(mmm/dd/yyyy)*
1.			_____/____/_______	_____/____/_______
2.			_____/____/_______	_____/____/_______
3.			_____/____/_______	_____/____/_______
4.			_____/____/_______	_____/____/_______
5.			_____/____/_______	_____/____/_______
6.			_____/____/_______	_____/____/_______
7.			_____/____/_______	_____/____/_______
8.			_____/____/_______	_____/____/_______
9.			_____/____/_______	_____/____/_______
10.			_____/____/_______	_____/____/_______

HISTORY OF CHRONIC MACROLIDE USE
(> 90 days of continuous therapy) from birth to Baseline Visit

0☐ None

Line #	Medication	Route *(IV, PO)*	Start Date *(mmm/dd/yyyy)*	Stop Date *(mmm/dd/yyyy)*
1.			_____/____/_______	_____/____/_______
2.			_____/____/_______	_____/____/_______
3.			_____/____/_______	_____/____/_______
4.			_____/____/_______	_____/____/_______
5.			_____/____/_______	_____/____/_______
6.			_____/____/_______	_____/____/_______
7.			_____/____/_______	_____/____/_______
8.			_____/____/_______	_____/____/_______
9.			_____/____/_______	_____/____/_______
10.			_____/____/_______	_____/____/_______

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PSEUDOMONAS AERUGINOSA CULTURE HISTORY ≤ 3 YEARS PRIOR TO BASELINE VISIT

Date of participant's qualifying documented *Pa* positive respiratory culture **prior to EPIC-001 Baseline Visit**: Date: _____/_____/__________ (*mmm* / *dd* / *yyyy*)

Was this the participant's first documented lifetime *Pa* positive respiratory culture? 0☐ No 1☐ Yes

If No, please list the participant's respiratory culture results (*Pa* positive or *Pa* negative) ≤ 3 years prior to the EPIC-001 Baseline Visit.

Line #	Culture Date (*mmm/dd/yyyy*)	*Pa* Results
1.	_____/____/_______	0☐ Negative 1☐ Positive
2.	_____/____/_______	0☐ Negative 1☐ Positive
3.	_____/____/_______	0☐ Negative 1☐ Positive
4.	_____/____/_______	0☐ Negative 1☐ Positive
5.	_____/____/_______	0☐ Negative 1☐ Positive
6.	_____/____/_______	0☐ Negative 1☐ Positive
7.	_____/____/_______	0☐ Negative 1☐ Positive
8.	_____/____/_______	0☐ Negative 1☐ Positive
9.	_____/____/_______	0☐ Negative 1☐ Positive
10.	_____/____/_______	0☐ Negative 1☐ Positive
11.	_____/____/_______	0☐ Negative 1☐ Positive
12.	_____/____/_______	0☐ Negative 1☐ Positive
13.	_____/____/_______	0☐ Negative 1☐ Positive
14.	_____/____/_______	0☐ Negative 1☐ Positive
15.	_____/____/_______	0☐ Negative 1☐ Positive

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PSEUDOMONAS AERUGINOSA CULTURE HISTORY ≤ 3 YEARS PRIOR TO BASELINE VISIT

Date of participant's qualifying documented *Pa* positive respiratory culture **prior to EPIC-001 Baseline Visit**: Date: _____/_____/_________ (mmm dd yyyy)

Was this the participant's first documented lifetime *Pa* positive respiratory culture? 0☐ No 1☐ Yes

If No, please list the participant's respiratory culture results (*Pa* positive or *Pa* negative) ≤ 3 years prior to the EPIC-001 Baseline Visit.

Line #	Culture Date *(mmm/dd/yyyy)*	*Pa* Results
1.	_____/____/_______	0☐ Negative 1☐ Positive
2.	_____/____/_______	0☐ Negative 1☐ Positive
3.	_____/____/_______	0☐ Negative 1☐ Positive
4.	_____/____/_______	0☐ Negative 1☐ Positive
5.	_____/____/_______	0☐ Negative 1☐ Positive
6.	_____/____/_______	0☐ Negative 1☐ Positive
7.	_____/____/_______	0☐ Negative 1☐ Positive
8.	_____/____/_______	0☐ Negative 1☐ Positive
9.	_____/____/_______	0☐ Negative 1☐ Positive
10.	_____/____/_______	0☐ Negative 1☐ Positive
11.	_____/____/_______	0☐ Negative 1☐ Positive
12.	_____/____/_______	0☐ Negative 1☐ Positive
13.	_____/____/_______	0☐ Negative 1☐ Positive
14.	_____/____/_______	0☐ Negative 1☐ Positive
15.	_____/____/_______	0☐ Negative 1☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PSEUDOMONAS AERUGINOSA CULTURE HISTORY > 3 YEARS PRIOR TO BASELINE VISIT

Has the participant had any *Pa* positive respiratory cultures > 3 years prior to the EPIC-001 Baseline Visit? 0☐ No 1☐ Yes 96☐ Unknown

If Yes, please list dates of all prior *Pa* **positive** respiratory culture results > 3 years prior to the EPIC-001 Baseline Visit.

Line #	Culture Date *(mmm/dd/yyyy)*
1.	_____/____/_______
2.	_____/____/_______
3.	_____/____/_______
4.	_____/____/_______
5.	_____/____/_______
6.	_____/____/_______
7.	_____/____/_______
8.	_____/____/_______
9.	_____/____/_______
10.	_____/____/_______
11.	_____/____/_______
12.	_____/____/_______
13.	_____/____/_______
14.	_____/____/_______
15.	_____/____/_______

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PSEUDOMONAS AERUGINOSA CULTURE HISTORY > 3 YEARS PRIOR TO BASELINE VISIT

Has the participant had any *Pa* positive respiratory cultures > 3 years prior to the EPIC-001 Baseline Visit? 0☐ No 1☐ Yes 96☐ Unknown

If Yes, please list dates of all prior *Pa* **positive** respiratory culture results > 3 years prior to the EPIC-001 Baseline Visit.

Line #	Culture Date *(mmm/dd/yyyy)*
1.	_____/____/_______
2.	_____/____/_______
3.	_____/____/_______
4.	_____/____/_______
5.	_____/____/_______
6.	_____/____/_______
7.	_____/____/_______
8.	_____/____/_______
9.	_____/____/_______
10.	_____/____/_______
11.	_____/____/_______
12.	_____/____/_______
13.	_____/____/_______
14.	_____/____/_______
15.	_____/____/_______

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

VITAL SIGNS

97☐ Not Done

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1☐ °C 2☐ °F

HEIGHT AND WEIGHT

Height 97☐ Not Done

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing 2☐ Prone

Weight 97☐ Not Done

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing 2☐ Sitting

Is the participant transitioning to standing? 0☐ No 1☐ Yes*

***If Yes**, please record second measurement below.

Height 98☐ N/A

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing

Weight 98☐ N/A

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing

PREGNANCY TEST

Was a pregnancy test required? 0☐ No 1☐ Yes

If Yes, record the results: 0☐ Negative 1☐ Positive 97☐ Not Done*

*If test required and not done, a comment is required in the Investigator Comment Log.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PHYSICAL EXAM

97 ☐ Physical Exam Not Done

Body Code	Body System	Normal	Abnormal	Not Done	Specify Abnormality
1.	General	0 ☐	1 ☐	97 ☐	
2.	Skin	0 ☐	1 ☐	97 ☐	
3.	Lymph Nodes	0 ☐	1 ☐	97 ☐	
4.	HEENT	0 ☐	1 ☐	97 ☐	
5.	Respiratory/ Chest	0 ☐	1 ☐	97 ☐	
6.	Cardiovascular	0 ☐	1 ☐	97 ☐	
7.	Gastrointestinal	0 ☐	1 ☐	97 ☐	
8.	Genitourinary	0 ☐	1 ☐	97 ☐	
9.	Musculoskeletal	0 ☐	1 ☐	97 ☐	
10.	Neurologic	0 ☐	1 ☐	97 ☐	

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

JOINT EXAM

97☐ Not Done

Joint Exam Findings

0☐ Normal
1☐ Abnormal*

If checked abnormal, describe findings and contributing factors:

____

____

____

Note: Chronic joint disease, such as JRA, may disqualify participant from study eligibility under exclusion criteria #10.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

SPIROMETRY 97 ☐ Not Done 98 ☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV$_1$: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0 ☐ No* 1 ☐ Yes	______/______/__________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum	0 ☐ No 1 ☐ Yes	______/______/__________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0 ☐ No 1 ☐ Yes Date prescribed: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

SERUM CHEMISTRY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
Creatinine	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
GGT	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
AST (SGOT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
ALT (SGPT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete Medical History CRF.

RESEARCH LABS

Serum for Serology / Banking

*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.

Tube One Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Two Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Three Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Tube Four Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

HEMATOLOGY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
RBC	98☐		$x10^6$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hematocrit	98☐		%		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hemoglobin	98☐		g/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Platelets	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
WBC	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Differential:							
Neutrophil Segs	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophil Bands	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophils (Combined Segs/Bands)	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Lymphocytes	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Monocytes	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Eosinophils	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Basophils	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Other:							
C-Reactive Protein	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion

*** Please complete Medical History CRF.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

CHEST RADIOGRAPH

97 ☐ Not Done

Chest radiograph findings:

Date of Chest Radiograph: _____/_____/__________
mmm dd yyyy

0 ☐ Normal
1 ☐ Abnormal; not clinically significant*
2 ☐ Abnormal; clinically significant*

*If checked abnormal, describe findings: ____

____

____

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

AUDIOLOGY 97☐ Not Done 98☐ N/A (at Site) Date tested: _____/_____/_________
mmm dd yyyy

Were the results interpretable? 0☐ No 1☐ Yes

If Yes, indicate the type of testing performed:

1☐ **Visual** Reinforcement Audiometry (VRA) 0☐ Normal 1☐ Abnormal*

*If Abnormal, complete the information below:

Warble Tones in Soundfield (dBHL)				
500 Hz	**1000 Hz**	**2000 Hz**	**4000 Hz**	**6000 Hz**
db	db	db	db	db

2☐ **Play** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

3☐ **Standard** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

PARTICIPANT FOLLOW-UP CONTACT

Baseline Visit plus 3 Days (+/- 2 Days)

Was the Participant randomized? 0☐ No 1☐ Yes

If Yes, 1☐ Cycled 2☐ Culture-based

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Start of Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Date study treatment started **(Day 0)**: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 2**

MICROBIOLOGY

Date of Visit: _____/_____/_________
mmm dd yyyy

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	Time Specimen Collected *(24-Hr Clock)*	*Pa* Result**	Isolate sent to: CHRMC Micro Lab
OP Swab	0 ☐ No* 1 ☐ Yes	_____/_____/________	___ ___:___ ___	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	0 ☐ No 1 ☐ Yes
Expectorated Sputum	0 ☐ No 1 ☐ Yes	_____/_____/________	___ ___:___ ___	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	0 ☐ No 1 ☐ Yes

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from Site Microbiology Laboratory.

LAST DOSE OF TOBI

Date *(mmm/dd/yyyy)*	Time *(24-Hr Clock)*
_____/_____/_________	___ ___:___ ___

TREATMENT

Treatment prescribed: 0 ☐ No 1 ☐ Yes Date prescribed: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 2**

PARTICIPANT FOLLOW-UP CONTACT

Visit 2 plus 3 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Start of Visit 2 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes 98☐ N/A

If Yes, Date: _____/_____/_________
mmm dd yyyy

Visit 2 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 3**

VITAL SIGNS

97 ☐ Not Done

Date of Visit: _____/_____/_________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1 ☐ °C 2 ☐ °F

HEIGHT AND WEIGHT

Height 97 ☐ Not Done

___ ___ ___.___ 1 ☐ cm 2 ☐ in 1 ☐ Standing 2 ☐ Prone

Weight 97 ☐ Not Done

___ ___ ___.___ 1 ☐ kg 2 ☐ lb 1 ☐ Standing 2 ☐ Sitting

Is the participant transitioning to standing? 0 ☐ No 1 ☐ Yes*

***If Yes**, please record second measurement below.

Height 98 ☐ N/A

___ ___ ___.___ 1 ☐ cm 2 ☐ in 1 ☐ Standing

Weight 98 ☐ N/A

___ ___ ___.___ 1 ☐ kg 2 ☐ lb 1 ☐ Standing

PREGNANCY TEST

Has fertility status changed for female participant? 0 ☐ No 1 ☐ Yes 98 ☐ N/A

Was a pregnancy test done? 0 ☐ No 1 ☐ Yes

If Yes, record the results: 0 ☐ Negative 1 ☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 3**

PHYSICAL EXAM

97 ☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Skin	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Lymph Nodes	0 ☐	1 ☐	2 ☐	97 ☐	
4.	HEENT	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Respiratory/ Chest	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Gastrointestinal	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Neurologic	0 ☐	1 ☐	2 ☐	97 ☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 3**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT BASELINE VISIT

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 2

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 3**

SPIROMETRY 97☐ Not Done 98☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV_1: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0☐ No* 1☐ Yes	_____/_____/_________	0☐ Negative 1☐ Positive 98☐ NAV
Expectorated Sputum	0☐ No 1☐ Yes	_____/_____/_________	0☐ Negative 1☐ Positive 98☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0☐ No 1☐ Yes Date prescribed: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 3**

PARTICIPANT FOLLOW-UP CONTACT

Visit 3 plus 7 Days (+/- 2 Days)

Was the Participant contacted? 0 ☐ No 1 ☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Start of Visit 3 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0 ☐ No 1 ☐ Yes 98 ☐ N/A

If Yes, Date: _____/_____/__________
mmm dd yyyy

Visit 3 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0 ☐ No 1 ☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

VITAL SIGNS

97 ☐ Not Done

Date of Visit: _____/_____/_________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1 ☐ °C 2 ☐ °F

HEIGHT AND WEIGHT

Height 97 ☐ Not Done

___ ___ ___.___ 1 ☐ cm 2 ☐ in   1 ☐ Standing 2 ☐ Prone

Weight 97 ☐ Not Done

___ ___ ___.___ 1 ☐ kg 2 ☐ lb   1 ☐ Standing 2 ☐ Sitting

Is the participant transitioning to standing? 0 ☐ No 1 ☐ Yes*

*__If Yes__, please record second measurement below.

Height 98 ☐ N/A

___ ___ ___.___ 1 ☐ cm 2 ☐ in   1 ☐ Standing

Weight 98 ☐ N/A

___ ___ ___.___ 1 ☐ kg 2 ☐ lb   1 ☐ Standing

PREGNANCY TEST

Has fertility status changed for female participant? 0 ☐ No 1 ☐ Yes 98 ☐ N/A

Was a pregnancy test done? 0 ☐ No 1 ☐ Yes

If Yes, record the results: 0 ☐ Negative 1 ☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

PHYSICAL EXAM 97☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0☐	1☐	2☐	97☐	
2.	Skin	0☐	1☐	2☐	97☐	
3.	Lymph Nodes	0☐	1☐	2☐	97☐	
4.	HEENT	0☐	1☐	2☐	97☐	
5.	Respiratory/ Chest	0☐	1☐	2☐	97☐	
6.	Cardiovascular	0☐	1☐	2☐	97☐	
7.	Gastrointestinal	0☐	1☐	2☐	97☐	
8.	Genitourinary	0☐	1☐	2☐	97☐	
9.	Musculoskeletal	0☐	1☐	2☐	97☐	
10.	Neurologic	0☐	1☐	2☐	97☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

JOINT EXAM 97☐ Not Done

Joint Exam Findings

0☐ Normal
1☐ Abnormal△*•

△Is this worsened from previous visit? 0☐ No 1☐ Yes

*If checked abnormal, describe findings and contributing factors:

____

____

____

Referred to Rheumatology? 0☐ No 1☐ Yes

If Yes, Date examined: _____/_____/__________
mmm dd yyyy

•*Please record AE if new findings or if worsened*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 3

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

SPIROMETRY

97 ☐ Not Done 98 ☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV_1: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0 ☐ No* 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum	0 ☐ No 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0 ☐ No 1 ☐ Yes Date prescribed: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

SERUM CHEMISTRY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
Creatinine	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
GGT	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
AST (SGOT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
ALT (SGPT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete AE form

RESEARCH LABS

Serum for Serology / Banking

*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.

Tube One Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Two Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Three Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Tube Four Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

HEMATOLOGY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
RBC	98☐		x10⁶/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hematocrit	98☐		%		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hemoglobin	98☐		g/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Platelets	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
WBC	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Differential:							
Neutrophil Segs	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophil Bands	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophils (Combined Segs/Bands)	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Lymphocytes	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Monocytes	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Eosinophils	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Basophils	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Other:							
C-Reactive Protein	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete AE form

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 4**

PARTICIPANT FOLLOW-UP CONTACT

Visit 4 plus 7 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Start of Visit 4 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes 98☐ N/A

If Yes, Date: _____/_____/_________
mmm dd yyyy

Visit 4 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 5**

VITAL SIGNS

97☐ Not Done

Date of Visit: _____/_____/_________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1☐ °C 2☐ °F

HEIGHT AND WEIGHT

Height 97☐ Not Done

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing 2☐ Prone

Weight 97☐ Not Done

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing 2☐ Sitting

Is the participant transitioning to standing? 0☐ No 1☐ Yes*

***If Yes**, please record second measurement below.

Height 98☐ N/A

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing

Weight 98☐ N/A

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing

PREGNANCY TEST

Has fertility status changed for female participant? 0☐ No 1☐ Yes 98☐ N/A

Was a pregnancy test done? 0☐ No 1☐ Yes

If Yes, record the results: 0☐ Negative 1☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 5**

PHYSICAL EXAM 97 ☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Skin	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Lymph Nodes	0 ☐	1 ☐	2 ☐	97 ☐	
4.	HEENT	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Respiratory/ Chest	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Gastrointestinal	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Neurologic	0 ☐	1 ☐	2 ☐	97 ☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 5**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 4

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 5**

SPIROMETRY

97 ☐ Not Done 98 ☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV_1: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0 ☐ No* 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum	0 ☐ No 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0 ☐ No 1 ☐ Yes Date prescribed: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 5**

PARTICIPANT FOLLOW-UP CONTACT

Visit 5 plus 7 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Start of Visit 5 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes 98☐ N/A

If Yes, Date: _____/_____/__________
mmm dd yyyy

Visit 5 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

VITAL SIGNS

97☐ Not Done

Date of Visit: _____/_____/_________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1☐ °C 2☐ °F

HEIGHT AND WEIGHT

Height 97☐ Not Done

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing 2☐ Prone

Weight 97☐ Not Done

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing 2☐ Sitting

Is the participant transitioning to standing? 0☐ No 1☐ Yes*

***If Yes**, please record second measurement below.

Height 98☐ N/A

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing

Weight 98☐ N/A

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing

PREGNANCY TEST

Has fertility status changed for female participant? 0☐ No 1☐ Yes 98☐ N/A

Was a pregnancy test done? 0☐ No 1☐ Yes

If Yes, record the results: 0☐ Negative 1☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

PHYSICAL EAM 97☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0☐	1☐	2☐	97☐	
2.	Skin	0☐	1☐	2☐	97☐	
3.	Lymph Nodes	0☐	1☐	2☐	97☐	
4.	HEENT	0☐	1☐	2☐	97☐	
5.	Respiratory/ Chest	0☐	1☐	2☐	97☐	
6.	Cardiovascular	0☐	1☐	2☐	97☐	
7.	Gastrointestinal	0☐	1☐	2☐	97☐	
8.	Genitourinary	0☐	1☐	2☐	97☐	
9.	Musculoskeletal	0☐	1☐	2☐	97☐	
10.	Neurologic	0☐	1☐	2☐	97☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

JOINT EXAM

97 ☐ Not Done

Joint Exam Findings

0 ☐ Normal
1 ☐ Abnormal△*•

△Is this worsened from previous visit? 0 ☐ No 1 ☐ Yes

*If checked abnormal, describe findings and contributing factors:

____

____

____

Referred to Rheumatology? 0 ☐ No 1 ☐ Yes

If Yes, Date examined: _____/_____/_________
mmm dd yyyy

•*Please record AE if new findings or if worsened*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 5

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

SPIROMETRY

97 ☐ Not Done   98 ☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV_1: ___.___ ___ (L)   FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0 ☐ No* 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum	0 ☐ No 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0 ☐ No   1 ☐ Yes   Date prescribed: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

SERUM CHEMISTRY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
Creatinine	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
GGT	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
AST (SGOT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
ALT (SGPT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete AE form

RESEARCH LABS

Serum for Serology / Banking

*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.

Tube One Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Two Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Three Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Tube Four Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

HEMATOLOGY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
RBC	98☐		x10⁶/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hematocrit	98☐		%		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hemoglobin	98☐		g/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Platelets	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
WBC	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Differential:							
Neutrophil Segs	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophil Bands	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophils (Combined Segs/Bands)	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Lymphocytes	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Monocytes	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Eosinophils	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Basophils	98☐		x10³/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Other:							
C-Reactive Protein	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion

*** Please complete AE form

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

AUDIOLOGY 97☐ Not Done 98☐ N/A (at Site) Date tested: _____/_____/__________
mmm dd yyyy

Were the results interpretable? 0☐ No 1☐ Yes

If Yes, indicate the type of testing performed:

1☐ **Visual** Reinforcement Audiometry (VRA) 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Warble Tones in Soundfield (dBHL)				
500 Hz	**1000 Hz**	**2000 Hz**	**4000 Hz**	**6000 Hz**
db	db	db	db	db

2☐ **Play** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

3☐ **Standard** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 6**

PARTICIPANT FOLLOW-UP CONTACT

Visit 6 plus 7 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Start of Visit 6 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes 98☐ N/A

If Yes, Date: _____/_____/__________
mmm dd yyyy

Visit 6 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/__________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 7**

VITAL SIGNS 97☐ Not Done

Date of Visit: _____/_____/_________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1☐ °C 2☐ °F

HEIGHT AND WEIGHT

Height 97☐ Not Done
1☐ cm 1☐ Standing
___ ___ ___.___ 2☐ in 2☐ Prone

Weight 97☐ Not Done
1☐ kg 1☐ Standing
___ ___ ___.___ 2☐ lb 2☐ Sitting

Is the participant transitioning to standing? 0☐ No 1☐ Yes*
***If Yes**, please record second measurement below.

Height 98☐ N/A
1☐ cm 1☐ Standing
___ ___ ___.___ 2☐ in

Weight 98☐ N/A
1☐ kg 1☐ Standing
___ ___ ___.___ 2☐ lb

PREGNANCY TEST

Has fertility status changed for female participant? 0☐ No 1☐ Yes 98☐ N/A

Was a pregnancy test done? 0☐ No 1☐ Yes

If Yes, record the results: 0☐ Negative 1☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 7**

PHYSICAL EXAM

97 ☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Skin	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Lymph Nodes	0 ☐	1 ☐	2 ☐	97 ☐	
4.	HEENT	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Respiratory/ Chest	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Gastrointestinal	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Neurologic	0 ☐	1 ☐	2 ☐	97 ☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 7**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 6

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 7**

SPIROMETRY 97☐ Not Done 98☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV$_1$: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected (mmm/dd/yyyy)	*Pa* Result**
OP Swab	0☐ No* 1☐ Yes	______/______/__________	0☐ Negative 1☐ Positive 98☐ NAV
Expectorated Sputum	0☐ No 1☐ Yes	______/______/__________	0☐ Negative 1☐ Positive 98☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

TREATMENT

Treatment prescribed: 0☐ No 1☐ Yes Date prescribed: _____/_____/__________
mmm dd yyyy

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Visit 7**

PARTICIPANT FOLLOW-UP CONTACT

Visit 7 plus 7 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Start of Visit 7 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted? 0☐ No 1☐ Yes 98☐ N/A

If Yes, Date: _____/_____/_________
mmm dd yyyy

Visit 7 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted? 0☐ No 1☐ Yes

If Yes, Date: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

VITAL SIGNS

97☐ Not Done

Date of Visit: _____/_____/__________
mmm dd yyyy

Heart Rate *(per min)*	Respirations *(per min)*	Blood Pressure *(mm Hg)*	Temperature
___ ___ ___	___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___.___ 1☐ °C 2☐ °F

HEIGHT AND WEIGHT

Height 97☐ Not Done

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing 2☐ Prone

Weight 97☐ Not Done

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing 2☐ Sitting

Is the participant transitioning to standing? 0☐ No 1☐ Yes*

*__If Yes__, please record second measurement below.

Height 98☐ N/A

___ ___ ___.___ 1☐ cm 2☐ in 1☐ Standing

Weight 98☐ N/A

___ ___ ___.___ 1☐ kg 2☐ lb 1☐ Standing

PREGNANCY TEST

Has fertility status changed for female participant? 0☐ No 1☐ Yes 98☐ N/A

Was a pregnancy test done? 0☐ No 1☐ Yes

If Yes, record the results: 0☐ Negative 1☐ Positive

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

PHYSICAL EAM

97 ☐ Physical Exam Not Done

Body Code	Body System	Change				Only Comment If Changed From Previous Visit (Improved or Worsened)
		No Change	Improved	Worsened*	Not Done	
1.	General	0 ☐	1 ☐	2 ☐	97 ☐	
2.	Skin	0 ☐	1 ☐	2 ☐	97 ☐	
3.	Lymph Nodes	0 ☐	1 ☐	2 ☐	97 ☐	
4.	HEENT	0 ☐	1 ☐	2 ☐	97 ☐	
5.	Respiratory/ Chest	0 ☐	1 ☐	2 ☐	97 ☐	
6.	Cardiovascular	0 ☐	1 ☐	2 ☐	97 ☐	
7.	Gastrointestinal	0 ☐	1 ☐	2 ☐	97 ☐	
8.	Genitourinary	0 ☐	1 ☐	2 ☐	97 ☐	
9.	Musculoskeletal	0 ☐	1 ☐	2 ☐	97 ☐	
10.	Neurologic	0 ☐	1 ☐	2 ☐	97 ☐	

*If worsened, record AE.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

JOINT EXAM

97 ☐ Not Done

Joint Exam Findings

0 ☐ Normal
1 ☐ Abnormal△*•

△Is this worsened from previous visit? 0 ☐ No 1 ☐ Yes

*If checked abnormal, describe findings and contributing factors:

____

____

____

Referred to Rheumatology? 0 ☐ No 1 ☐ Yes

If Yes, Date examined: _____/_____/_________
mmm dd yyyy

•*Please record AE if new findings or if worsened*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 7

98 ☐ N/A

Medication	Formulation and Dose Prescribed	Start Date Stop Date *(mmm/dd/yyyy)*	# / Amount Dispensed *(from Rx container label)*	# / Amount Returned
TOBI	1 ☒ Vials 1 ☐ 300 mg/ 5 ml	_____/_____/_________ _____/_____/_________	_______ vials	_______ vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	_____/_____/_________ _____/_____/_________	______tablets	______tablets
	3 ☐ Suspension 6 ☐ 100 mg/ 1 ml BID 7 ☐ 150 mg/ 1.5 ml BID 8 ☐ 200 mg/ 2 ml BID 9 ☐ 250 mg/ 2.5 ml BID 10 ☐ 375 mg/ 3.75 ml BID 11 ☐ 500 mg/ 5 ml BID 12 ☐ 750 mg/ 7.5 ml BID	_____/_____/_________ _____/_____/_________	________mls	*(Estimate liquid volume from side of Rx bottle for suspension)* ________mls

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

SPIROMETRY 97☐ Not Done 98☐ N/A

Spirometry

FVC: ___.___ ___ (L) FEV$_1$: ___.___ ___ (L) FEF 25-75%: ___.___ ___ (L/sec)

MICROBIOLOGY

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* Result**
OP Swab	0☐ No* 1☐ Yes	_____/_____/_________	0☐ Negative 1☐ Positive 98☐ NAV
Expectorated Sputum	0☐ No 1☐ Yes	_____/_____/_________	0☐ Negative 1☐ Positive 98☐ NAV

* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
** *Pa* results from CHRMC Core Microbiology Laboratory.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

SERUM CHEMISTRY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
Creatinine	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
GGT	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
AST (SGOT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
ALT (SGPT)	98☐		U/L		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete AE form

RESEARCH LABS

Serum for Serology / Banking

*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.

Tube One Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Two Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50

Tube Three Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Tube Four Volume 0☐ 0.00 1☐ 0.01-0.25 2☐ 0.26-0.50 3☐ 0.51-0.75 4☐ 0.76-1.00

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

HEMATOLOGY

Was the specimen collected? 0☐ No* 1☐ Yes

*If a specimen was not collected, a comment is required in the Investigator Comment Log.

Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal and Clinically Significant)***
RBC	98☐		$x10^6$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hematocrit	98☐		%		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Hemoglobin	98☐		g/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Platelets	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
WBC	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Differential:							
Neutrophil Segs	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophil Bands	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Neutrophils (Combined Segs/Bands)	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Lymphocytes	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Monocytes	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Eosinophils	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Basophils	98☐		$x10^3$/uL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	
Other:							
C-Reactive Protein	98☐		mg/dL		1☐ Low 2☐ Normal 3☐ High	0☐ No 1☐ Yes	

** According to investigator's opinion
*** Please complete AE form

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

CHEST RADIOGRAPH

97 ☐ Not Done

Chest Radiograph Findings

Date of Radiograph: _____/_____/_________
mmm dd yyyy

Chest radiograph interpretation:

0 ☐ Normal
1 ☐ Abnormal; not clinically significant*
2 ☐ Abnormal; clinically significant*

**If checked abnormal, describe findings:* ____

____

____

Comparison to Baseline:

0 ☐ No Change
1 ☐ Improved
2 ☐ Worsened•

•*Record AE if worsened since Baseline*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**End of Study Visit**

AUDIOLOGY 97☐ Not Done 98☐ N/A (at Site) Date tested: _____/_____/_________
mmm dd yyyy

Were the results interpretable? 0☐ No 1☐ Yes

If Yes, indicate the type of testing performed:

1☐ **Visual** Reinforcement Audiometry (VRA) 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Warble Tones in Soundfield (dBHL)				
500 Hz	**1000 Hz**	**2000 Hz**	**4000 Hz**	**6000 Hz**
db	db	db	db	db

2☐ **Play** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

3☐ **Standard** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

HOSPITALIZATION

0 ☐ No Hospitalization

Line No.	Admission Date *(mmm/dd/yyyy)*	Discharge Date *(mmm/dd/yyyy)*	Diagnosis
1.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
2.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
3.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
4.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
5.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
6.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:
7.	______/____/________	______/____/________	1 ☐ Pulmonary Exacerbation 99 ☐ Other *(describe)*:

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

CONCOMITANT MEDICATIONS AND THERAPIES

Record any medication or therapy the Participant is using ≤ 30 days prior to the Baseline Visit. Record any changes to or new medications or therapies (excluding study medications) that occur during the course of the study.

Line No.	Medication / Therapy (Brand or Generic)	Indication	Dose	Units	Frequency[a]	Route[b]	>30 Days[c]	Start Date Stop Date	
					If "99=Other" please specify	If "99=Other" please specify		*(mmm/dd/yyyy)* mark box (✓) if continuing ↓	
1.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other ______			☐ ______	☐ ______	1 ☐	___/___/_____ ___/___/_____	1 ☐
2.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other ______			☐ ______	☐ ______	1 ☐	___/___/_____ ___/___/_____	1 ☐
3.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other ______			☐ ______	☐ ______	1 ☐	___/___/_____ ___/___/_____	1 ☐
4.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other ______			☐ ______	☐ ______	1 ☐	___/___/_____ ___/___/_____	1 ☐
5.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other ______			☐ ______	☐ ______	1 ☐	___/___/_____ ___/___/_____	1 ☐

[a]**Frequency**: 1 = QD, 2 = BID, 3 = TID, 4 = QID, 5 = QHS, 6 = QOD, 7 = PRN, 99 = Other

[b]**Route**: 1 = Oral, 2 = Intravenous, 3 = Subcutaneous, 4 = Intramuscular, 5 = Nasal, 6 = Topical, 7 = Gastrointestinal Tube, 8 = Nasogastric, 9 = Rectal, 10 =Inhaled, 11 = Intradermal, 12 = Vaginal, 13 = Intra-articular, 14 = Opthalmic, 15 = Intralesional, 99 = Other

[c]**>30 Days**: Check box if start date is more than 30 Days prior to the date of the Baseline Visit and leave start date blank.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

ADVERSE EVENTS

Has the participant experienced any adverse events? 0 ☐ No 1 ☐ Yes If Yes, describe below.

Line No.	Adverse Event	Start Date / Stop Date		Outcome	Any Treatment Required?	Severity[a]	Study Agent Action	Relation To Study Drug	Was Event Serious?[b]	Hospitalized?*
	(List one event per line)	*(mmm/dd/yyyy)* mark box (✓) if continuing ↓		1 = Unresolved 2 = Resolved 3 = Resolved w/Sequelae 4 = Death	0 = None 1 = Concomitant Medications 2 = Non-Drug Therapies 3 = Concomitant Medications and Non-Drug Therapies	1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening	0 = None 1 = Discontinued 2 = Stopped and Restarted	1 = Unrelated 2 = Possibly 3 = Probably 4 = Definitely	0 = No 1 = Yes	0 = No 1 = Yes
1.		____/____/______ ____/____/______	1 ☐							
2.		____/____/______ ____/____/______	1 ☐							
3.		____/____/______ ____/____/______	1 ☐							
4.		____/____/______ ____/____/______	1 ☐							

[a]Please refer to protocol for severity definitions.
[b]Please refer to protocol for serious adverse event (SAE) definitions. If “Yes” is marked, an SAE form must be completed.
*Please complete Hospitalization CRF.

This CRF data was not submitted

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

INVESTIGATOR COMMENT LOG

This form is to be used for explaining any relevant events occurring during the course of the study that are **NOT** noted elsewhere.

CRF Page	Visit	Comment

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

STUDY TERMINATION

Did the Participant complete the study 0 ☐ No 1 ☐ Yes

If No, Date of Withdrawal: _____/_____/_________
mmm dd yyyy

Select one reason *(below)* for withdrawal:

1 ☐ Screening failure

2 ☐ Participant discontinued due to an adverse event. Record adverse event on AE page.
Specify: ____

3 ☐ Participant decision (e.g., voluntary withdrawal, withdrawal of consent, compliance with study procedures), specify: ____

4 ☐ Physician decision, specify: ____

5 ☐ Lost to follow-up

6 ☐ Death

99 ☐ Other, specify: ____

This CRF data was not submitted

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___

INVESTIGATOR STATEMENT

I certify that I have carefully examined all entries on the Case Report Forms and that all information entered on these pages is correct.

Principal Investigator's Signature: ________________________________ Date: _____/_____/_________
mmm dd yyyy

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

MICROBIOLOGY

Study Visit this Supplemental CRF page is associated with (e.g., Visit 3): ________________________

Specimen Type	Was Specimen Collected?	Date Specimen Collected *(mmm/dd/yyyy)*	*Pa* result**
OP Swab	0 ☐ No* 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum	0 ☐ No 1 ☐ Yes	_____/_____/_________	0 ☐ Negative 1 ☐ Positive 98 ☐ NAV

*If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.
***Pa* results from CHRMC Core Microbiology Laboratory.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

AUDIOLOGY 97☐ Not Done 98☐ N/A (at Site) Date tested: _____/_____/__________ (mmm dd yyyy)

Were the results interpretable? 0☐ No 1☐ Yes

If Yes, indicate the type of testing performed:

1☐ **Visual** Reinforcement Audiometry (VRA) 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Warble Tones in Soundfield (dBHL)				
500 Hz	**1000 Hz**	**2000 Hz**	**4000 Hz**	**6000 Hz**
db	db	db	db	db

2☐ **Play** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

3☐ **Standard** Audiometry Left Ear: 0☐ Normal 1☐ Abnormal* Right Ear: 0☐ Normal 1☐ Abnormal*

*If Abnormal, record AE and complete the information below:

Pure Tone Air Conduction Thresholds (dBHL)							
EAR	**500 Hz**	**1000 Hz**	**2000 Hz**	**3000 Hz**	**4000 Hz**	**6000 Hz**	**8000 Hz**
Right	db	db	db	db	db	db	db
Left	db	db	db	db	db	db	db

See version 2 of this page at the end of the document

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

SIGNS AND SYMPTOMS OF A PULMONARY EXACERBATION

Check a response for each criteria or signs/symptoms:

Major criteria:

- Decrease in FEV1 — 0☐ No 1☐ Yes 98☐ NAV
- Decreased Oxygen saturation — 0☐ No 1☐ Yes 98☐ NAV
- New lobar infiltrate or atelectasis — 0☐ No 1☐ Yes 98☐ NAV
- Hemoptysis — 0☐ No 1☐ Yes 98☐ NAV

Minor Signs/symptoms:

- Increased work of breathing/respiratory rate — 0☐ No 1☐ Yes 98☐ NAV
- New or increased adventitial sounds on lung exam — 0☐ No 1☐ Yes 98☐ NAV
- Weight loss — 0☐ No 1☐ Yes 98☐ NAV
- Increased cough — 0☐ No 1☐ Yes 98☐ NAV
- Decreased exercise tolerance or level of activity — 0☐ No 1☐ Yes 98☐ NAV
- Increased chest congestion or change in sputum — 0☐ No 1☐ Yes 98☐ NAV

Duration Criteria:

- Duration of sign/symptoms $\geq$5 days — 0☐ No 1☐ Yes 98☐ NAV

Do the criteria, signs/symptoms, and duration listed above meet the definition of pulmonary exacerbation per the study protocol? 0☐ No 1☐ Yes

If Yes, date of diagnosis: _____/_____/__________ (*mmm* *dd* *yyyy*)

Was the participant hospitalized? 0☐ No 1☐ Yes*

Admission date: _____/_____/__________ (*mmm* *dd* *yyyy*)

Were intravenous antibiotics required? 0☐ No 1☐ Yes**

Date IV antibiotic therapy started: _____/_____/__________ (*mmm* *dd* *yyyy*)

Were oral antibiotics required? 0☐ No 1☐ Yes**

Date oral antibiotic therapy started: _____/_____/__________ (*mmm* *dd* *yyyy*)

Were inhaled antibiotics required? 0☐ No 1☐ Yes**

Date inhaled antibiotic therapy started: _____/_____/__________ (*mmm* *dd* *yyyy*)

* *Please record on Hospitalization CRF*

** *Please record on Conmeds CRF*

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

PHYSICIAN INITIATED TREATMENT DISCONTINUATION

Study drug discontinuation:

1 ☐ TOBI[▵]

*Date discontinued: ______/______/__________
mmm dd yyyy

1 ☐ Temporary
2 ☐ Permanent

▵If TOBI has been discontinued, please record Ciprofloxacin discontinuation.

*Please describe reason for discontinuation: ____

____

____

2 ☐ Ciprofloxacin/placebo

*Date discontinued: ______/______/__________
mmm dd yyyy

1 ☐ Temporary
2 ☐ Permanent

*Please describe reason for discontinuation: ____

____

____

The CRF data for this page was not submitted.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

EPIC OBSERVATIONAL STUDY (EPIC-002)

Has the participant enrolled in the EPIC Observational Study (EPIC-002)? 0☐ No 1☐ Yes

If Yes, Date of Enrollment: ______/______/___________
mmm dd yyyy

Observational Study ID number: ____________________

Version 2 of INCLUSION CRITERIA

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Baseline**

INCLUSION CRITERIA

	No	Yes	N/A
1. Male or female ≥ 1 year and ≤ 12 years of age	0 ☐	1 ☐	
2. Confirmed diagnosis of Cystic Fibrosis: • sweat chloride > 60 mEq/L by quantitative pilocarpine iontophoresis; and/or • a genotype with two identifiable mutations consistent with CF or an abnormal nasal transepithelial potential difference **and** • one or more clinical features consistent with CF	0 ☐	1 ☐	
3. ***Participants >15 months of age:** New onset of *Pa* positive respiratory culture within 6 months prior to Baseline Visit:			98 ☐
a) first lifetime documented *Pa* positive culture; **OR**	0 ☐	1 ☐	98 ☐
b) *Pa* recovered after at least a 2 year history of *Pa* negative respiratory cultures (≥ 1 culture/year)	0 ☐	1 ☐	98 ☐
4. ***Participants 12-15 months of age:** at least one documented *Pa* positive respiratory tract culture since birth or CF diagnosis	0 ☐	1 ☐	98 ☐
5. Clinically stable: • no evidence of significant respiratory symptoms and/or physical or chest radiograph findings at screening that would require administration of IV anti-pseudomonal antibiotics, oxygen, and/or hospitalization	0 ☐	1 ☐	
6. Signed informed consent by parent or legal guardian and applicable assent.	0 ☐	1 ☐	

**Select appropriate age criteria for participant. If participant is >15 months of age, also select either subcriteria a) or b).*

Version 2 of Pulmonary Exacerbation signs and symptoms

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001	___ ___ ___	___ ___ ___	___ ___ ___	**Supplemental**

SIGNS AND SYMPTOMS OF A PULMONARY EXACERBATION

Date Symptoms Started: _____/_____/__________
mmm dd yyyy

Check a response for each criteria or signs/symptoms:

Major criteria:

- Decrease in FEV1 — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Decreased Oxygen saturation — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- New lobar infiltrate or atelectasis — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Hemoptysis — 0 ☐ No 1 ☐ Yes 98 ☐ NAV

Minor Signs/symptoms:

- Increased work of breathing/respiratory rate — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- New or increased adventitial sounds on lung exam — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Weight loss — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Increased cough — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Decreased exercise tolerance or level of activity — 0 ☐ No 1 ☐ Yes 98 ☐ NAV
- Increased chest congestion or change in sputum — 0 ☐ No 1 ☐ Yes 98 ☐ NAV

Duration Criteria:

- Duration of sign/symptoms $\geq$5 days — 0 ☐ No 1 ☐ Yes 98 ☐ NAV

Do the criteria, signs/symptoms, and duration listed above meet the definition of pulmonary exacerbation per the study protocol? — 0 ☐ No 1 ☐ Yes

If Yes, date of diagnosis: _____/_____/__________
mmm dd yyyy

Was the participant hospitalized? — 0 ☐ No 1 ☐ Yes*

Admission date: _____/_____/__________
mmm dd yyyy

Were intravenous antibiotics required? — 0 ☐ No 1 ☐ Yes**

Date IV antibiotic therapy started: _____/_____/__________
mmm dd yyyy

Were oral antibiotics required? — 0 ☐ No 1 ☐ Yes**

Date oral antibiotic therapy started: _____/_____/__________
mmm dd yyyy

Were inhaled antibiotics required? — 0 ☐ No 1 ☐ Yes**

Date inhaled antibiotic therapy started: _____/_____/__________
mmm dd yyyy

* *Please record on Hospitalization CRF*

** *Please record on Conmeds CRF*